

## **REMARKS**

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 1 to 21 and 28 to 31, all other claims having been cancelled.

Claims 1 to 18, 20, 21 and 28 to 30 stand rejected under 35 USC 102 as being anticipated by the El et al reference. The Examiner is of the opinion that the claims read upon a copolymer comprising at least one non-cross-linked polysaccharide and at least one non-polysaccharide non-cross-linked polymer. With respect to Applicants' second argument, the Examiner is interpreting the claim as being a product-by-process claim which does not distinguish over the prior art and since the building elements of the copolymer of the reference are the same as that of the instant claims, it must be the same product.

Applicants respectfully traverse this ground of rejection since the El et al reference does anticipate or render obvious Applicants' invention. As pointed out in the application as filed, the El et al reference uses a process which consists of mixing the polycarboxylic polymers of the polysaccharidic and non-polysaccharidic in an aqueous

solution wherein in a final cross-linked copolymer of heterogeneities resulting with the cross-linking reactions between the polysaccharides only or between the non-polysaccharidic carboxylic polymers only. The present invention is intended to obviate this problem and to exclude the formation of heterogeneities. This problem is solved by first reaction the copolymers of the two starting types, namely, the polysaccharide polymer on the one hand and the non-saccharidic polymer (one being polycarboxylic) on the other hand to link the two by means of a covalent bond to form a non-cross-linked polycarboxylic copolymer and the non-cross-linked copolymer is then reacted with a cross-linking agent to form a cross-linked copolymer which avoids the formation of the heterogeneities. These cross-linked copolymers based upon the non-cross-linked polycarboxylic copolymers is distinct from the type of polymers obtained by the El et al reference. Therefore, the same does not anticipate or render obvious Applicants' invention and withdrawal of this ground of rejection is requested.

Applicants' have the advantages of being able to modulate the properties of the cross-linked copolymer such as the hydrophily and they can be obtained with appropriate degradation properties as a function of their use. The polymer are useful in pharmaceutical compositions wherein the active ingredient can be any compound or substance having a therapeutic activity and are useful for the sustained release of the active ingredient in the colon, for instance, by the action of the microbial flora. The building elements of Applicants' cross-linked copolymers are different from that of the El

et al reference wherein the beginning polymer is not cross-linked and since the building elements are different, the cross-linked copolymers are necessarily different. Therefore, withdrawal of this ground of rejection is requested.

Claim 19 remains rejected under 35 USC 103 as being obvious over the El et al reference taken in view of the Heidel patent.


Applicants respectfully traverse this ground of rejection since, as noted in the last response, the Lambert et al patent is the national phase of the El et al reference cited by the Examiner and discussed above and therefore, it does not anticipate or render obvious Applicants' invention for the reasons that the El et al reference does not anticipate or render obvious Applicants' invention.

In order to more clearly point out the distinctions between the prior art cited by the Examiner and the present invention, Applicants are submitting herewith a table illustrating the differences between the prior art cited by the Examiner and the present invention. As can be seen from the table, the copolymer of the prior art is at least one polycarboxylic polysaccharide and at least one other non-cross-linked polycarboxylic polymer which is not a polycarboxylic polysaccharide and each building element of the copolymer is a polycarboxylic acid, one element being a polysaccharide and the other is a non-polysaccharide. In contrast thereto, Applicants have two non-cross-linked

copolymers, one being a polysaccharide and one being a non-polysaccharide and the two are linked by a covalent bond to form a non-cross-linked polycarboxylic copolymer wherein at least one of the two elements is polycarboxylic and these monomers are then reacted with a cross-linking agent to form a cross-linked copolymer. Therefore, it is believed clear that the references are in no way related to Applicants' invention and withdrawal of these grounds of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,  
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CAM:ds  
Enclosures

# Comparison between the PCT application WO 98/08897 and the present patent application

|                   | WO 98/08897   | Present application US 10/089,287   |
|-------------------|---|---|
| Final compound    | Cross-linked copolymers   | Cross-linked copolymers   |
| Building elements | Non cross-linked polycarboxylic polymers<br>+ reticulating agent comprising at least 2 amine functions<br><br>[cf the wording of the claim 1 of the PCT :<br>"Copolymères réticulés à base de polymères polycarboxyliques non réticulés, ..."   | Non cross-linked polycarboxylic <u>copoly</u> mers<br>+ reticulating agent comprising at least 2 amine functions  |
| Characteristics   | The copolymer comprises<br>i) at least one polycarboxylic polysaccharide<br>ii) at least one other non cross-linked polycarboxylic polymer which is not a polycarboxylic polysaccharide<br>In order to obtain the reticulation, each building element of the copolymer is a polycarboxylic element, one element is a polysaccharide and the other one is not a polysaccharide | - each non cross-linked polycarboxylic copolymer comprises at least one non cross-linked polysaccharide linked by a covalent bond to at least one other non saccharidic non cross-linked polymer.<br>- at least one of the polysaccharides and non saccharidic polymers constituting the same non cross-linked copolymer, is polycarboxylic.<br><br>In the following examples illustrating the present invention, one building element (= non cross-linked polycarboxylic copolymer) is called "(a)" and the other one "(b)".<br><u>Example 1:</u><br>- copolymer (a) is based on a polycarboxylic polysaccharide linked by |

polycarboxylic polysaccharide

reticulating agent

polycarboxylic polymer  
(which is not a polysaccharide)

covalent bond to a non-polycarboxylic polymer (which is a non-saccharidic polymer)

- copolymer (b) is based on a non-polycarboxylic polysaccharide linked by a covalent bond to a polycarboxylic polymer (which is a non-saccharidic polymer)

non-polycarboxylic polymer      polycarboxylic polysaccharide

(a)

reticulating agent

(b) -----

non-polycarboxylic polysaccharide      polycarboxylic polymer

Example 2:

- copolymer (a) is based on a polycarboxylic polysaccharide linked by covalent bond to a non-polycarboxylic polymer (which is a non-saccharidic polymer)

- copolymer (b) is based on a polycarboxylic polysaccharide linked by covalent bond to a non-polycarboxylic polymer (which is a non-saccharidic polymer)

non-polycarboxylic polymer      polycarboxylic polysaccharide

(a)

reticulating agent

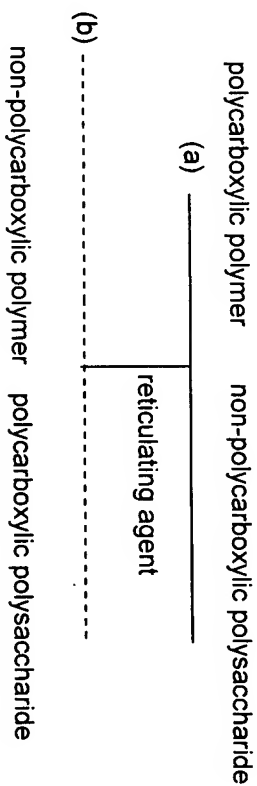
(b) -----

non-polycarboxylic polymer      polycarboxylic polysaccharide

Example 3:

- copolymer (a) is based on a non-polycarboxylic polysaccharide linker by a covalent bond to a polycarboxylic polymer (which is a non-saccharidic polymer)

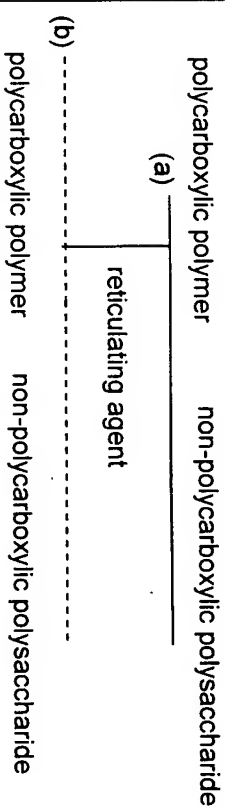
- copolymer (b) is based on a polycarboxylic polysaccharide linked by covalent bond to a non-polycarboxylic polymer (which is a non-saccharidic polymer)



Example 4:

- copolymer (a) is based on a non-polycarboxylic polysaccharide linker by a covalent bond to a polycarboxylic polymer (which is a non-saccharidic polymer)

- copolymer (b) is based on a non-polycarboxylic polysaccharide linker by a covalent bond to a polycarboxylic polymer (which is a non-saccharidic polymer)



|  |  |   |
|--|--|---|
|  |  | <p>In each of these examples, the reticulation is present between the polycarboxylic element of (a) and the polycarboxylic element of (b), (a and (b) being block copolymers.</p> <p>Finally, in the examples 2 and 4 :</p> <ul style="list-style-type: none"> <li>- the polymer of the building element (a) and the polymer of the building element (b) are not necessarily the same ; and</li> <li>- the polysaccharide of the building element (a) and the polysaccharide of the building element (b) are not necessarily the same.</li> </ul> |
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